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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,452	06/10/2001	Kazuo Sugamura	2001-0572A	4276

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EXAMINER

KAPUST, RACHEL B

ART UNIT PAPER NUMBER

1647

DATE MAILED: 12/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,452

Applicant(s)

SUGAMURA ET AL.

Examiner

Rachel B. Kapust

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 6-12 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 13 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group 1, claims 1-5 and 13, in Paper No. 0903 is acknowledged. Claims 6-12 and 14 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.48(b).

Claims 1-5 and 13 are under consideration.

Information Disclosure Statement

The references cited in the Search Report received May 10, 2001 have been considered, but will not be listed on any patent resulting from this application because they were not provided on a separate list in compliance with 37 CFR 1.98(a)(1). In order to have the references printed on such resulting patent, a separate listing, preferably on a PTO-1449 form, must be filed within the set period for reply to this Office action.

Claim Rejections - 35 USC § 101

Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 is drawn to a human protein hAMSH and claims 2-4 are drawn to DNA encoding the human protein hAMSH, all of which are unaltered, naturally occurring articles. Thus, they are not articles of "manufacture." These rejections may be obviated by amending the claims to read "an isolated human protein" or "an isolated human gene" so long as there is support for the amendment in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant disclosure of two nucleic acid sequences, SEQ ID NOS: 2 and 4, does not adequately describe the scope of the claimed genus, which encompasses hundreds of thousands of different polynucleotide sequences. The genus as disclosed by Applicants encompasses polynucleotides comprising a "partial sequence" of SEQ ID NO: 2. There are neither limits as to the length of a partial sequence nor limits as to the function of the partial sequence or peptides encoded by the partial sequence. Applicants have not described any common characteristics linking these different polynucleotides so that the skilled artisan could identify which ones would be members of a genus of polynucleotides having similar properties. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The specification at best invites persons skilled in the art to identify those polynucleotide sequences that function in the manner desired. One skilled in the art would not be able to visualize or recognize the identity of the full scope of polynucleotide sequences claimed. Therefore, the specification does not provide an adequate written description of the subject matter claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Yu *et al.* (1997, *Genome Res.* 7(4): 353-358, submitted by Applicants May 10, 2001). Yu *et al.* teach a sequence that is 100% identical to SEQ ID NO: 2 of the current application over a span of 1356 base pairs (see GenBank Accession No. AF052135 (submitted March 5, 1998) and attached alignment spanning bp 1-1356 of SEQ ID NO: 2). Thus, claim 4 is anticipated by Yu *et al.*

Claims 4 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Andersson *et al.* (1996, *Anal. Biochem.* 236(1): 107-113, submitted by Applicants May 10, 2001). Andersson *et al.* teach a sequence that is 100% identical to SEQ ID NO: 2 of the current application over a span of 1356 base pairs (see GenBank Accession No. AF052135, submitted March 5, 1998). Furthermore, Andersson *et al.* teach inserting the DNA into vectors (p. 107, column 2). Thus, claims 4 and 13 are anticipated by Andersson *et al.*

Allowable Subject Matter

Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

NO CLAIMS ARE ALLOWED.

The following articles, patents, and published patent applications were found by the Examiner during the art search while not relied upon are considered pertinent to the instant application:

U.S. Patent No. 6,468,546

U.S. Pre-Grant Publication No. 2003/0073623

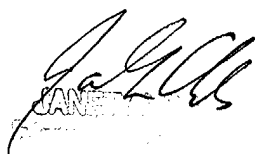
International Application WO 01/21794

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel B. Kapust whose telephone number is (703) 305-0634. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm. Please note for your records that after approximately January 20, 2004, the examiner's new telephone number will be (571) 272-0886.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RBK

A handwritten signature in dark ink, appearing to read 'R. Kapust', is written over a faint, rectangular stamp. The signature is fluid and cursive.